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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,183	11/22/2000	Susana Salceda	DEX-0117	1493

26259 7590 02/07/2002

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EXAMINER
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DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/721,183

Applicant(s)

SALCEDA ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Applicant's amendment filed 17 December 2001 (Paper No: 11) is acknowledged. Accordingly, claims 1 and 4-7 are amended and claims 1-17 are pending.

#### ***Response to Arguments***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Applicant's traversal of the election of Group III, claims 3-7 is acknowledged. The traversal is on the ground(s) that the inventions are not independent and distinct and may be examined without a serious burden because art relating to Group III should reveal art relating to the other Groups. This is not found persuasive for reasons indicated in the previous office action, as the Groups have different class/subclass, thus rendering them independent and distinct and a serious burden to search.

The requirement is still deemed proper and is therefore made FINAL. Claims 3-7 are being examined as belonging to the elected Group III, while claims 1-2 and 8-17 are withdrawn from examination as being drawn to a non-elected invention.

#### ***Specification***

2. Amendments to the specification and abstract have not been entered because a marked up copy was not submitted.

#### ***Specification Objections - Maintained***

3. Objection to the abstract and specification is maintained for reasons set for the in previous office action.

#### ***Claim Rejections - 35 USC § 112 2<sup>nd</sup> Withdrawn***

4. Rejection of claims 3-7 under 35 U.S.C.112, second paragraph is withdrawn in view of amendments.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Maintained***

5. Rejection of claims 3-7 under 35 U.S.C.112, first paragraph is maintained for reasons set forth in the previous office action. The traversal is on the grounds that the specification gives data evidencing a high level of tissue specificity as well as overexpression of BCSG-1, -2, -3 and -5 in breast cancer samples and one of skill in the art could extrapolate results as being indicative of breast cancer. Applicant's arguments have been considered but are not persuasive because the levels of BCSG in cancer tissue is increased, decreased, and not statistically different, when compared to normal tissue (Table 7). Accordingly, how would one be able to diagnose breast cancer, when BCSG levels are decreased when compared to normal tissue and how would one specifically diagnose breast cancer when BCSG levels are increased in cancer tissue from various organs when compared to normal tissue?

6. The specification indicates that BCSG refers to both native proteins and polynucleotides (p. 7). The claims are broadly drawn to measuring BCSG levels, which includes proteins and polynucleotides and applicant is only enabled for determining BCSG levels using nucleic acid based assays, wherein the mRNA is measured because the specification has not give any guidance or exemplification that BCSG protein is expressed and determining protein expressions levels is indicative of diagnoses, staging, and monitoring. Thus, it would be an undue burden to one of ordinary skill in the art to assay for BCSG levels beyond using nucleic acid based assays because applicant has not shown that the BCSG protein is expressed and increased expression levels are indicative of a breast cancer diagnosis.

7. An article by Alberts, et al. is cited in order to establish the general state of the art and the level of predictability of protein translation. Those of skill in the art, recognize that expression of mRNA does not dictate the translation of such mRNA into a polypeptide. Alberts, et al. (Molecular Biology of the Cell, 3rd edition, 1994, page 465) teach that translation of ferritin mRNA into ferritin polypeptide is blocked during periods of iron starvation. Likewise, if excess iron is available, the transferrin receptor mRNA is degraded and no transferrin receptor polypeptide is translated. Many other proteins are regulated at the translational level rather than the transcriptional level. Thus, predictability of protein translation is not necessarily contingent on mRNA expression due to the multitude of homeostatic factors affecting transcription and

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translation. Therefore, one of skill in the art would not be able to predict if the nucleic acids of BCSG were in fact translated into protein. One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to determining BCSG levels. Accordingly, it would be an undue burden and unpredictable for one of ordinary skill in the art to assay for BCSG protein levels. The claims may be allowable if they were to recite "determining levels of BCSG mRNA or polynucleotide" or some other language that is supported by the specification, which indicates polynucleotide levels are determined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, PhD  
February 7, 2002

  
GEETHA P. BANSAL  
PRIMARY EXAMINER